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WIGGIN AND DANA LLP
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1646	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/685,757	NAKAJIMA, SHINYA	
	Examiner	Art Unit	
	Bruce D. Hissong, Ph.D.	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) *5-11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 October 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/15/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Formal matters

1. The contents of the instant application, including the claims, specification, abstract, drawings, and oath and declaration, were received on 10/15/2003, and have been entered into the record.

2. Claims 1-11 are currently pending. Claims 5-11 have been withdrawn as being non-elected subject matter; therefore claims 1-4 are the subject of this Office Action.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, drawn to a medicine including interferon, and methods of preparing said medicine, classified in class 424, subclass 85.4.

II. Claims 5-11, drawn to an administering systems of medicines including interferon, classified in class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

Inventions 1 and 2 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, an administering system for medicines can be practiced with virtually any type of medicine.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Elizabeth Galletta on 12/16/2005 a provisional election was made, while retaining the right to traverse, to prosecute the invention of group 1, claims 1-4. Affirmation of this election must be made by the applicant in replying to this Office Action. Additionally, if Applicant desires to traverse the restriction requirement, grounds for traversal must be presented in the reply to this Office Action. Claims 5-11 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Priority

The instant application claims priority to application 2002-311571, filed in Japan on 10/25/2002. Acknowledgment is made of Applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). However, a certified copy of parent application 2002-311571 has NOT been received. Therefore, the earliest effective filing date for the instant application has been determined to be 10/15/2003. However, if Applicants do file a Certified English translation of parent application 2002-311571, the priority date will be reconsidered.

Information Disclosure Statement

The information disclosure statement filed on 10/15/2003 has been entered into the record, and has been fully considered by the Examiner.

Drawings

The drawings are objected to because the figures lack sufficient descriptive features to allow interpretation. Specifically, the Y-axis labels on Figures 3 and 4 are vague and require further detail/description. Furthermore, the description of the figures in the specification lacks appropriate detail. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of

an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The specification is objected to for the following informalities. Page 3, paragraph 0009 of the specification describes a figure, but does not state specifically which figure is being described. Similarly, on page 9, paragraph 00033, line 3, the abscissa axis of Figure 4 is described as using (-) to mean results before interferon (IFN) administration, and (.) to mean after IFN administration. This description is inconsistent with Figure 4, which shows symbols of (-) and (+) on the abscissa axis. Appropriate correction is required.

Claim Objections

Claims 1-4 are objected to because of the following informalities: The claims recite a medicine *including* interferon. The intended meaning of the term "including" is not clear.

Claim Rejections - 35 USC § 112, first paragraph - enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a medicine including IFN, and a method for the

preparation of said medicine, whereby the IFN is the IFN-α of Figures 2-4, does not reasonably provide enablement for a medicine including any other type of IFN. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims

The factors to be considered when determining if the disclosure satisfies the enablement requirement have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breath of claims. Ex Parte Forman, (230 USPQ 546 (Bd. Pat. App. & Int. 1986); In re Wands, 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

The claims are drawn to a medicine including interferon, and methods of preparing said medicine. The families of molecules that make up the human interferons consist of type II interferons, namely IFN-γ, and type I interferons, which consist of IFN-β, IFN-ω and IFN-α family members (Pestka, 2001, Biopolymers, Vol 55, No. 4, p. 254). Recently, IFN-λ1, -λ2, and –λ3 were also identified (Kotenko et al, 2003, Nat Immunol, Vol 4, No. 1, p. 69-77). In addition, human IFN-α is known to consist of multiple family members with distinct activities (Pestka, p. 257-262, and Tables II and III). The breadth of the claims, therefore, is excessive because the claims, by reciting only "interferon", read on all types of interferons. The specification, on page 4, paragraph 00015, states that "any kinds of IFN are suitable for the present invention". However, for the reasons set forth above, a person of ordinary skill in the art would not know which IFN family members, other than the IFN-α of figures 2-4, are capable of being used commensurate in scope with the claims. Although the specification does state that the use of IFN-α and IFN-β is preferred, and does provide some guidance and examples concerning the use of IFN-α in figures 2-4, there is no teaching of which specific IFN-α family member(s) are useful in the present invention. Furthermore, there is no guidance or working examples of any other IFN family member. The skilled artisan would not be able to predict which of the many IFN-α family members, other than the IFN-α used in figures 2-4, some of which possess distinct biological activities, could be used in the present invention without undue experimentation.

Therefore, due to the breadth of the claims that read on any IFN, the lack of guidance and working examples in the specification that teach the use of other IFN family members, and the unpredictability of the art regarding the biological activities of every IFN family member, a

person of ordinary skill in the art would not know how to make and use the invention with any IFN other than the IFN-α of figures 2-4 without further, undue experimentation.

2. Claims 1-2 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the IFN-α receptor of figure 2, and peripheral blood mononuclear cells, does not reasonably provide enablement for a method of detecting any other IFN receptor in a cell type that is not a peripheral blood mononuclear cell. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 1-2 are drawn to a method of preparation of medicines comprising the steps of detecting the number of IFN receptors, and of measuring the amount of 2'-5'-oligoadenylate synthetase (2-5AS) in a cell. The language of the claims reads on any type of IFN receptor. However, the specification does not teach, or provide examples showing that all types of IFN receptors can be used in this method. The specification does show reduced IFN-α binding after IFN treatment, but does not present any evidence that any IFN receptor other than the IFN-α receptor of figure 2 (e.g. type II IFN receptors) is downregulated in a similar manner. A person of ordinary skill in the art would not be able to predict the dosage of IFN in the medicine of claims 1-2 without knowing the behavior of all types of IFN receptors.

Similarly, the specification does not provide any guidance or working examples that teach which cell types can be used in the method of the instant invention. The specification does recite peripheral blood mononuclear cells (p. 3, paragraph 00010). Peripheral blood mononuclear cells, however, encompass several cell types, including T and B lymphocytes, as well as monocyte-lineage cells. Although it is well known in the art that the type I IFN receptor is ubiquitously expressed in almost all cell types, the expression of type II IFN receptors is restricted to cells of the immune system. Furthermore, the expression of 2-5AS in response to type II IFN varies in regard to the target cell type. It has been long known in the art that type I IFNs are potent inducers of 2-5AS activity in most cell types. However, type II IFN does not induce 2-5AS activity in all cell types, and in particular does not induce 2-5AS activity in T lymphocytes (Zucca et al, 1988, J Biol Regul Homeost Agent, Vol 2, p. 15-18). Thus, although the specification does recite the use of peripheral blood mononuclear cells, a skilled artisan still would be unable to predict the effects of any IFN on 2-5AS induction because, as stated above, peripheral blood mononuclear cells represent a heterogenous population of cells that do not

respond to all IFNs in the same way. The choice of cell type to be used in the method of the instant application, in addition to the type of IFN, can therefore profoundly affect the results obtained in said method. There is no guidance or working examples in the specification that teach any other IFN receptors, or any other cell types, and therefore, a person of ordinary skill in the art would not be able to predict the effect of all types of IFNs, in all possible cell types, on the expression of all possible IFN receptors, and on the induction of 2-5AS activity. It would require undue experimentation for the skilled artisan to be able to determine the amount of any IFN to include in a medicine without first knowing how to correlate the effects of all IFNs in all cell types with regards to IFN receptor expression and 2-5AS activity.

In summary, due to the breadth of the claims, which read on a method involving any cell type expressing any type of IFN receptor, the lack of guidance and examples in the specification which would teach a skilled artisan how to use any cell type and IFN, and the unpredictability of the art regarding the expression of different IFN receptors in any cell type, a skilled artisan would not be able to make and use the instant invention without undue experimentation.

Claim Rejections - 35 USC § 112, first paragraph – written description

Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a medicine including interferon, and a method of preparing said medicine. The claims do not specify a particular type of IFN to be used in the medicine of the instant application, and as stated in the above enablement rejection, the term IFN encompasses many types of molecules. In particular, IFN-α is made up of a number of distinctly different polypeptides. Thus, the claims are drawn to the use of a genus of biologically active polypeptides in that is defined only by the ability to bind to an IFN receptor and induce 2-5AS activity.

The claims are also drawn to a method of preparing a medicine including IFN, comprised of determining the number of IFN receptors on the surface of any cell, and further determining 2-5AS activity in any cell. The claims do not specify a particular cell type, or a particular IFN receptor (i.e. type I or II IFN receptors) that can be used in the claimed method. The claims only

assert that the method involves determining the number of IFN receptors on, or 2-5AS activity in, a cell. Thus, the claims are drawn to the use of a genus of cell types, and a genus of IFN receptors.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claims is a requirement that the medicine include "interferon". There is no identification of any particular type of IFN that can be used, other than the IFN-α of figures 2-4, nor is there any recitation of a particular type if IFN receptor to be measured, or any particular cell type to be used in the assay other than peripheral blood mononuclear cells. Accordingly, in the absence of sufficient distinguishing characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only the IFN-α of figures 2-4, the IFN receptors of figure 2, and peripheral blood mononuclear cells, but not the full breadth of the claims, meets the written description

provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are drawn to a medicine, or method of preparing said medicine, *including* interferon. It is not clear to the examiner if the phrase "including interferon" means that interferon is one of several possible medicines, or if the medicine of claims 1-4 is *comprised* of interferon (i.e. the intended meaning of the term "including" is "comprising"). Appropriate clarification is required.

2. Claims 1 and 2 recite the limitation "the cell" in the method of preparing a medicine including IFN. There is insufficient antecedent basis for this limitation in the claim. Similarly, claim 4 recites "the amount" in the recitation of the IFN dosage. There is insufficient antecedent basis for this limitation in the claim.

3. Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The claims recite a method for preparation of medicine, comprising the first step of detecting the number of interferon receptors on the surface of the cell (claim1), and wherein the first step is characterized by measuring the value that corresponds to the amount of 2-5AS induced in the cell (claim 2). The omitted steps are: a correlation step that shows how the determination of 2-5AS activity, and the numbers of IFN receptors on the surface of a cell, allows a skilled artisan to determine the IFN dosage of a medicine and, therefore, to prepare a medicine.

4. Claims 1 and 2 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a stimulation step, whereby the cells of the method are stimulated with IFN. The specification, as well as the prior art, teaches that IFN receptors and 2-5AS levels are altered *in response* to IFN stimulation. The method of the claims does not recite a step in which the cells are stimulated with IFN in order to alter IFN receptor levels and induce 2-5AS activity.

5. Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The claims recite a method for preparation of medicine including interferons, comprising the first step of detecting the number of IFN receptors on the surface of the cell, and also a step of measuring IFN-induced 2-5AS activity in the cell. As stated above in 112, second paragraph, rejection 1, the intended meaning of the term "including" is not clear. The claims, therefore, can be interpreted as medicines in addition to IFN. In the context of this interpretation, the claims are missing a method step showing how a skilled artisan would be able to correlate IFN receptor levels and 2-5AS activity to determine the dosage of any medicine other than IFN.

6. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The meaning of the phrase "more than the amount so that the expected outstanding effects of interferon are exerted" is not clear to the Examiner. Clarification is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by

> another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 3 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Albrecht and Grint (US 6,387,365). The claims are drawn to a medicine including IFN that is prepared so that the IFN dose is less than 3 million IU in each administration. Albrecht and Grint teach a method of treating hepatitis C by administration of IFN-α, and specifically IFN-α-2b, at a dose that is less than 3 million IU, and further teach that administering lower doses will minimize the side effects of IFN-a treatment (column 2, lines 32-40, and claim 1). Thus, thus disclosure of Albrecht and Grint meet the limitations of claims 3 and 4 of the instant application.

2. Claims 3 and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Yanai et al (US 6,773,701). The claims are drawn to a medicine including IFN that is prepared so that the IFN dose is less than 3 million IU in each administration. Yanai et al teach pharmaceutical preparations of IFNs that contain less than 3 million IU (see column 12, lines 43-56), thus meeting the limitations of claims 3 and 4 of the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uno *et al*, in view of Kawamura *et al* (Hepato-Gastroentrology, 1999, Vol 46, p. 2941-2945). Claims 1 and 2 of the instant application are drawn to a method of preparing a medicine including IFN, comprising the steps of detecting the number of IFN receptors on a cell, further determining the level of 2-5AS activity in the cell, and subsequently determining the dosage of IFN according to the number of IFN receptors and the level of 2-5AS activity. Uno *et al* disclose a method for determining 2-5AS activity, and teach using this method to design therapeutic protocols but does not teach the determination of IFN receptors to design therapeutic protocols. Kawamura

et al specifically teach an inverse relationship between IFN-induced 2-5AS activity and IFN receptor expression on IFN-treated cells (see Figure 1). Although Kawamura does not specifically teach determining the dosage of a medicine including IFN by measuring IFN receptor numbers, a person of ordinary skill in the art would be motivated to combine the teachings of Uno *et al* with those of Kawamura *et al* to practice the invention of claims 1 and 2. Because Kawamura *et al* firmly establishes a relationship between IFN-induced 2-5AS activity and IFN receptor expression, the skilled artisan would know that if therapeutic protocols can be predicted by determining 2-5AS activity, then IFN-induced IFN receptor expression would also represent a reliable method for the design of therapeutic protocols. Therefore, a person of ordinary skill in the art would not only have the motivation to combine the teachings of Uno *et al* with those of Kawamura *et al* to practice the invention of claims 1 and 2, but also a reasonable expectation of success. Because the design of therapeutic protocols certainly encompasses determination of IFN dosage in a medicine, claims 1 and 2 are unpatentable, for the reasons set forth above, over Uno *et al* in view of Kawamura *et al*.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce D. Hissong, Ph.D. whose telephone number is (571) 272-3324. The examiner can normally be reached M-F from 8:30am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (571) 272-0829. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BDH
Art Unit 1646

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PRIMARY EXAMINER